

777 SOUTH FLAGLER DRIVE, WEST TOWER, SUITE 1500, WEST PALM BEACH, FL 33401
TEL 561/820-9900 • FAX 561/832-2297
1 2 6 3 99 FEB -2 P 3:39

BARBARA E. WAITMAN General Counsel LEGAL DEPARTMENT 767 THIRD AVENUE NEW YORK, N.Y. 10017

> TEL 212/319-8181 FAX 212/319-0757



January 15, 1999

Elizabeth A. Yetley, Ph.D. Director
Office of Special Nutritionals (HFS – 450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, SW
Washington, D.C. 20204

Dear Dr. Yetley:

Pursuant to Section 403(r) (6) of the Dietary Supplement Health and Education Act of 1994, 21 CFR 101.93, and 63 FR 23633, Thompson Medical Company, Inc., 777 South Flagler Drive West, Suite 1500, West Palm Beach, Florida 33401, wishes to notify the Food and Drug Administration that it has commenced marketing a dietary supplement product, within the past 30 days, which bears statements of nutritional support.

The dietary supplement product will be distributed under the trade name Nature's Reward Heart Wise and will make the following statements of nutritional support:

- For Good Heart Health;
- Seven Herbs And Vitamins Combined In One Unique Formula To support A Healthy Heart;
- Folic Acid, Vitamins B-6 & B-12 help maintain healthy cardiovascular function;
- Vitamin E helps support a healthy heart; and

LET 2933 63292

975 - 0162

Hawthorne Extract – may help maintain a healthy circulatory system;

Please be advised that these statements are based on a large body of data, which, in our judgment, renders these statements substantiated, complete, accurate, truthful and not misleading. This product does not present a significant or unreasonable risk of illness or injury under the conditions of use recommended or suggested in the labeling. In addition, they are accompanied by the required disclaimer (*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease*) which is prominently displayed on the package in bold-faced type.

Sincerely,

Barbara E. Waitman

General Counsel

Heart Wise

Supplement Facts

Serving Size 2 Caplets

	Amount Per Serving	% Daily Value
Vitamin E (100% as natural d-alpha tocopherol succinate)	100 IU	335%
Vitamin B-6 (as pyridoxine hydrochloride)	3 mg	150%
Folic Acid	400 mcg	100%
Vitamin B-12 (as cyanocobalamin)	6 mcg	100%

Herbal blend

Hawthorn standardized extract (2.2% flavonoids, supplying 10 mg total flavonoids) (fruit and/or leaf and flower), green tea leaf standardized extract (36% polyphenols), standardized resveratrol (provides 2 mg resveratrol from *Polygonum cuspidatum* root and red wine grape concentrate) 600 mg

†Daily value not established.

OTHER INGREDIENTS: Dicalcium phosphate, cellulose, fractionated vegetable oil, silica.

STANDARDIZED EXTRACTS

- FOLIC ACID, VITAMINS B-6 & B-12 help maintain healthy cardiovascular function*
- VITAMIN E helps support a healthy heart*
- HAWTHORN EXTRACT may help maintain a healthy circulatory system*

*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

SUGGESTED USE: As a dietary supplement, take two Heart Wise caplets daily, preferably with a meal. IMPORTANT: This product is not intended for children. Do not take this product if you are pregnant or nursing a baby. If you have a medical condition or are taking any prescription medication, consult your doctor before using this product.

Store at controlled room temperature 15-30°C (59-86°F). Protect from heat, light and moisture.

BLISTER PACKED FOR YOUR PROTECTION Do not use if individual seals are broken.

MONEY BACK GUARANTEE: You must be completely satisfied with the results of this product, or you may return package with unused product to Thompson Medical Company for a full refund of your purchase price. Limit one money back guarantee per family or address.

THOMPSON MEDICAL CO., INC.

Made in





ITEM NO.

C8293

NEW: For Good Heart Health

Nature's Reward ** Heart Wise*

STANDARDIZED EXTRACTS

- FOLIC ACID, VITAMINS B-6 & B-12 help maintain healthy cardiovascular function*
- · VITAMIN E helps support a healthy heart*
- HAWTHORN EXTRACT may help maintain a healthy circulatory system*

A-0372-01



Seven Herbs And Vitamins
Combined In One Unique
Formula To Support
A Healthy Heart*

Heart Wise

•FOLIC ACID •VITAMINS B-6 & B-12
•VITAMIN E •3 HERBAL EXTRACTS

DIETARY SUPPLEMENT

30 CAPLETS

Mature's Reward"
Se

Heart Wise